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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/583,228	05/26/2000	Pawan Seth	8674-000004	2041

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EXAMINER	
WANG, SHENGJUN	
ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 09/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/583,228	SETH, PAWAN	
	Examiner	Art Unit	
	Shengjun Wang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 May 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6,9-14,19-22 and 24-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6,9-14,19-22,24-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt of applicants' amendments and remarks submitted May 19, 2004 is acknowledged.

Claim Rejections 35 U.S.C. 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4, 6, 9-14, 19-22, 24-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morella et al. (USPN 5,378,474).

Morella et al. (USPN 5,378,474) teaches a substantially similar composition as those claimed herein. Morella et al. ('USPN 5,378,474) teaches a sustained release pharmaceutical composition having a core element containing an antihypertensive agent such as Verapamil Hydrochloride, binding agent, such as PVD, modified celluloses, and other well known pharmaceutical carrier and excipients; a coating comprising a methacrylic polymer (1-30% wt., soluble at a pH from 6-7.5 in the intestines), hydroxypropyl methylcellulose (4-20% wt.), polyethylene glycol (15-35% wt.) and a filler such as silicon dioxide (4-30% wt.), see, particularly, claims 1, 2, 7 and 9 as well as Col.4, line 24. column 11, lines 3-33. Morella et al. (USPN 5,378,474) also teaches that the active ingredient in the pharmaceutical composition reaches its maximum concentration between about 4 and about 30 hours, col. 24, claim 1 and that the bioavailability of the active agents in the pharmaceutical pellet is not compromised by

food, col.7, lines 34-40. Morella discloses at least one polymer which is substantially insoluble at acidic pH (i.e., that of the stomach) but at least partially soluble at a less acidic to basic pH (i.e., the pH of the intestine), see col. 6, lines 43-52 col. 7 lines 34-62 in particular.

Morella et al. (USPN 5,378,474) does not teach the particular composition containing the specific ingredients in the amounts herein.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the particular composition containing the specific ingredients herein in amounts herein.

One of ordinary skill in the art would have been motivated to make the composition Claimed herein since a substantially similar composition is taught in the prior art. Morella et al. (USPN 5,378,474) teaches a similar composition which may contain an antihypertensive agent (including verapamil) and the excipients herein in amounts (wt. percentages) that overlap with those in the instant claims. The optimization of amounts of ingredients to be employed in a composition is considered within the skill of the artisan. The instant composition is not seen to patentably distinguish over the prior art, absent evidence to the contrary. No such evidence is

2. Seen. As to claims 26-50 reciting a intermediate coating which read on the same coating disclosed by Morella, note it would have been an obvious alternative for accomplish the coating by two steps instead of one step (i.e., coating two time with the same material). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The intermediate coating herein are construed as the same as the final coating.

Response to the Arguments

Applicants' amendemnts and remarks submitted May 19, 2004 have been fully considered, but are not persuasive.

Applicants argue that Morella reference does not teach or suggest verapamil composition free of food effect. The arguments are not convincing. Particularly, Morella specifically states "the relative bioavailability of the active ingredient generated from the pharmaceutical pellet composition is not compromised by food so that compliance will improve as the product may be taken without regard to meals." (column 7, lines 36-40) In view of the teaching, one of ordianrys kill in the art would understand that the composition would not be affected by food. If applicants' intension is to argue an unexpected benefit residing in the claimed invention, note a few notable principles are well settled. It is applicant's burden to explain any proffered data and establish how any results therein should be taken to be unexpected and significant. See MPEP 716.02 (b). The claims must be commensurate in the scope with any evidence of unexpected results. See MPEP 716.02 (d).

3. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., excluding the other polymer from the coating herein claimed) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The examiner does not see asserted "significant" difference between what disclosed in Morella and those herein claimed.

4. Applicant refers to formulations 1 and 2 of Morella to support the allegation that Morella do not teach "free of food effect." Note that formulations 1 and 2 have morphine, not verapamil as an active ingredient. Further note that the teachings of a prior art reference need to be taken ms a whole. Throughout the Morella reference, the Skilled Artisan can find that the composition is not compromised by food, see for example, col. 1, lines 35-39, col. 7, lines 34-40 for example. Further, there is no significant difference between "free of food effect" herein claimed and "the product may be taken without regard to meal" as disclosed by Morella.

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SHENGJUN WANG
PRIMARY EXAMINER

Shengjun Wang
Primary Examiner
Art Unit 1617